

Serial No.: 10/769,962

Filed: February 2, 2004

**REMARKS**

This paper is responsive to the final Office Action mailed January 10, 2007. Claims 1 and 3-31 are pending in the application. Claims 12-31 have been allowed. Claims 10 and 11 were objected to as being dependent upon a rejected base claim, but were indicated as allowable if rewritten in independent form. Claims 1 and 3-9 stand rejected.

Applicant appreciates the courtesies extended by Examiner Ali in the telephone interview held with the Applicants' undersigned representative on January 26, 2007. In the interview Applicants' representative asserted that claim 1, and the claims depending therefrom, are not unpatentable in view of the cited references. Specifically, Applicants' representative contended that the primary reference to Fauza (USP 6,612,305) does not teach or suggest a tracheostomy tube having a flange capable of selective attachment to the proximal end of the tube and detachment therefrom, as claimed in claim 1. The Examiner agreed to review the primary reference upon receipt of Applicants' Request for Reconsideration. No agreement was reached at the interview.

In the final Office Action, Claims 1, 8 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Fauza. Claim 3 was rejected under 35 USC §103(a) as being unpatentable over Fauza. Claims 4, 6 and 7 were rejected under 35 USC §103(a) as being unpatentable over Fauza in view of Roy (USP 6,135,110).

The viability of all rejections depends on the construction of the Fauza reference rendered by the Examiner. According to the Examiner (Page 2, Office Action of January 10, 2007),

Fauza discloses "selective attachment ("A movable flange (3) allows for extra fixation of the device around a patient's neck", see abstract, see also, Col. 4 lines 9-10) to said proximal end portion and detachment therefrom ....

Applicants respectfully disagree with the Examiner's characterization of the teachings of Fauza. Upon careful review of this reference, Applicants are unable to find any support for the contention that the flange in Fauza is selectively detachable (i.e., removable) from tracheostomy tube 2. For example, it is noted that are two reference lines in the figures from reference numeral "3" (reference number 3 refers to the flange).

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One reference line points to the radial extendable member that is commonly characterized in the art as a flange, and the other line points to a sleeve member that fits around the tracheostomy tube, and to which the radial extension is attached. The sleeve member appears to be a permanent structure on tube 2, and not removable from the tracheostomy tube. Similarly, there is no indication that the radial extendable member is removable from the sleeve member. Although it is not clear from the reference, it appears that the flange may be movable along the length of tube 2 by sliding sleeve 3 along at least a portion of the length of tube 2. In addition, although also not clear, it is possible that the "flat" portion of flange may be pivotable with reference to tube 2. In either event, there is no indication that flange 3 can be detached (removed), from tracheostomy tube 2.

Claim 1, as previously amended, is directed to a tracheostomy tube that comprises a hollow tubular body having a curved portion intermediate respective proximal and distal end portions. A flange situated at the proximal end portion is capable of *selective attachment to the proximal end portion and detachment therefrom*. The flange extends radially from the proximal end portion when attached thereto. Thus, unlike the flange described in Fauza, the flange of claim 1, as amended, is capable of selective attachment to and detachment from the proximal end of the hollow tubular body during a tracheostomy procedure.

Although other uses are contemplated, the inventive tracheostomy tube finds particular utility when used in combination with a radially expandable introducer sheath, such as the prior art sheath shown in Fig. 1 of the present application. When a radially expandable sheath of this type is utilized for the introduction therethrough of a tracheostomy tube that has a conventional flange projecting therefrom in the radial direction, it becomes difficult to withdraw the sheath following insertion and placement of the tracheostomy tube. In this instance, the flange portion of the tube is situated directly in the path of the withdrawing sheath, thereby obstructing the withdrawal of the sheath. By utilizing a flange that may be selectively attached to and detached from the proximal end of the tracheostomy tube during a tracheostomy procedure, the tube can be introduced into the trachea via the radially expandable sheath. Following placement of the tracheostomy tube, the introducer sheath can simply be withdrawn in the proximal

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direction over the tube. Since the flange has been removed from the tube, there is no radially extending structure present on the tube body that obstructs the withdrawal. Following removal of the introducer sheath, the flange can be attached, or reattached, to the tracheostomy tube.

The tracheostomy tube/flange combinations in Fauza do not teach or suggest this feature. Rather, Fauza teaches a "movable" neck flange. Contrary to the assertions of the Examiner in the Office Action, there is nothing in Fauza that suggests that this flange is capable of selective attachment to and detachment from the proximal end of the tube, as claimed. Rather, as stated above, the flange of Fauza appears to be simply movable or pivotable in some manner at the site of its attachment to the tube, in order to facilitate attachment of a strap. In the Office Action, the Examiner cited a portion of Fauza ("A movable flange (3) allows for extra fixation of the device around a patient's neck, see abstract, see also, col.4 lines 9-10)" as support for teaching a removable flange. However, Applicants respectfully submit that the cited portion of Fauza is referring to movement, or adjustment, of the flange in a manner such that a strap can be fixed around a patient's neck at different distances from the balloon, depending on the local anatomy of the patient. This passage from Fauza neither teaches nor suggests the selective attachment of the flange to, and/or detachment of the flange from, the proximal end portion of the tube. At most, Fauza teaches a flange that may be maneuvered in some manner to permit fixation of a strap around the neck of a patient. The Examiner seems to have equated a "movable" flange, with a detachable flange. Applicants respectfully submit that there is nothing in Fauza to suggest such an extension of the actual teaching of Fauza.

Based on the foregoing, Applicants respectfully submit that independent claim 1, as well as dependent claims 8 and 9, are not anticipated by Fauza.

Claim 3 was rejected under 35 USC §103(a) as being unpatentable over Fauza. Claims 4, 6 and 7 were rejected under 35 USC §103(a) as being unpatentable over Fauza in view of Roy (USP 6,135,110). Each of these claims is dependent, directly or indirectly, from independent claim 1. Therefore, each of these claims incorporates each of the limitations of claim 1, including the limitation of a tracheostomy tube having a flange capable of selective attachment to the proximal end portion of the tracheostomy

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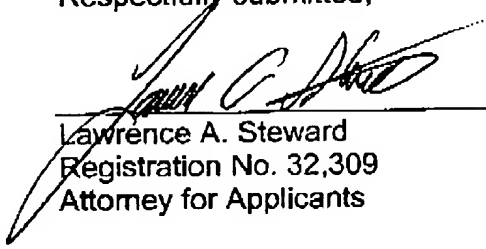
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tube and detachment therefrom. Neither Fauza nor Roy teaches or suggests a tracheostomy tube having a flange as described. Thus, Applicants respectfully submit that claims 2, 4, 6 and 7 are allowable for at least the same reasons that claims 1, 8 and 9 are allowable.

**Conclusion**

For the reasons provided hereinabove, Applicants respectfully request that the Examiner reconsider the rejections of claims 1 and 3-9, and following such reconsideration, issue a Notice of Allowance for all claims 1 and 3-31.

Respectfully submitted,

  
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